

UNITED STATES DISTRICT COURT

for the
Southern District of Florida

United States of America

v.

MIRIAM VALDEZ

Case No. **15-2833-JL**

Defendant(s)

CRIMINAL COMPLAINT

I, the complainant in this case, state that the following is true to the best of my knowledge and belief.

On or about the date(s) of June 16, 2015 in the county of Miami-Dade in the
Southern District of Florida, the defendant(s) violated:

Code Section

21 U.S.C. § § 331(t) and 333(a)(2)

Offense Description

Miriam VALDEZ did, with intent to defraud and mislead, act as an improper wholesale distributor of prescription drugs and fail to provide transaction history, transaction information, and transaction statements as required by 21 U.S.C. § 360eee-1(c) (1)(A)(iii) and in violation of 21 U.S.C. § 331(t) and 333 (a)(2).

This criminal complaint is based on these facts:

SEE ATTACHED AFFIDAVIT.

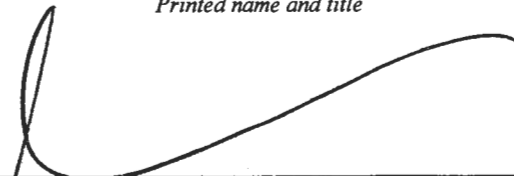
☒ Continued on the attached sheet.


Complainant's signature

CESAR D ZAYAS, FDA-OCI
Printed name and title

Sworn to before me and signed in my presence.

Date: 06/17/2015


Judge's signature

City and state: Miami, Florida

JONATHAN GOODMAN, U.S. MAG.JUDGE
Printed name and title

**AFFIDAVIT OF SPECIAL AGENT CESAR D. ZAYAS
IN SUPPORT OF CRIMINAL COMPLAINT**

I, CESAR D. ZAYAS, being duly sworn, depose and say:

A. INTRODUCTION

1. I am a Special Agent with the Office of Criminal Investigations ("OCI"), United States Food and Drug Administration ("FDA"), Miami Field Office, located in Plantation, Florida. I have been employed as a Special Agent with FDA/OCI since July 2013.

2. As a Special Agent with FDA/OCI, I have participated in numerous investigations concerning criminal violations of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq. (the "FDCA"), and other federal criminal laws.

3. I am a law enforcement officer of the United States, in that I am empowered under the authority of the FDCA to conduct investigations and to make arrests.

4. In my capacity as an FDA/OCI Special Agent, I have received extensive training in, among other things, investigations of counterfeit drugs, drug misbranding, drug diversion, drug adulteration, and drug tampering.

5. Prior to my current employment, I was a Special Agent with Department of State Bureau of Diplomatic Security Service (DSS) for approximately (4) years. Prior to my employment with DSS, I was employed with the Department of State Bureau of Consular Affairs for approximately two (2) years.

6. Your affiant has executed and assisted with numerous search warrants and criminal complaints, and is familiar with the probable cause standard for the issuance of a federal search warrant and a criminal complaint.

7. The statements contained in this affidavit are based in part on information provided by Special Agents with the Food and Drug Administration, Office of Criminal Investigations ("FDA/OCI"), other law enforcement officers, inspection results, and my experience and background as a special agent. Except where indicated, all statements referred to below are set forth in substance and in part, rather than verbatim.

8. I have set forth herein only such information as I believe necessary to establish probable cause to believe that Miriam VALDEZ committed several violations of federal law, to wit, diversion of prescription drugs by acting as an improper wholesale distributor of prescription drugs and, with intent to defraud and mislead, failing to provide transaction history, transaction information, and a transaction statement as required by 21 U.S.C. § 360eee-1(c)(1)(A)(iii).

B. FEDERAL LAW GOVERNING PRESCRIPTION DRUG DISTRIBUTION

9. On November 27, 2013, the Drug Supply Chain Security Act (DSCSA) was enacted to protect the integrity of the nation's drug distribution system. Effective January 1, 2015, the FDCA, as amended by the DSCSA, imposes several requirements on wholesale distributors of most prescription drugs, including certain product tracing requirements. Specifically, wholesale distributors of prescription drugs who did not purchase a prescription drug product directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer must, prior to or at the time of each transaction, provide to the subsequent

purchaser a transaction history, transaction information, and transaction statement. 21 U.S.C. 360eee-1(c)(1)(A)(iii).¹

10. Transaction history means a statement in paper or electronic form that includes the transaction information for each prior transaction going back to the manufacturer of the drug product. 21 U.S.C. § 360eee (25). Transaction information includes, among other things, the strength and dosage form of the drug product, the number of containers, the lot number of the drug product, the business name and address of the persons from whom and to whom ownership is being transferred. 21 U.S.C. § 360eee (26). Transaction statement means a statement in paper or electronic form that the entity transferring ownership of a drug product is in compliance with certain provisions of the DSCSA. 21 U.S.C. § 360eee (27).

11. The failure to provide the transaction statement, transaction history, and transaction information as required by 21 U.S.C. § 360eee-1(c)(1)(A)(iii) is a prohibited act under the FDCA.. See 21 U.S.C. § 331(t). If the offense is committed with intent to defraud or mislead, the offense is a felony punishable by up to three years in prison for each count,

¹ On December 31, 2014, FDA issued a Compliance Policy Guidance that announced that FDA did not intend to take action against trading partners, including wholesale drug distributors, who did not prior to May 1, 2015 provide transaction history, transaction information, and transaction statement as required by the DSCSA.

PROBABLE CAUSE

C. CONTROLLED BUYS OF PRESCRIPTION DRUGS FROM TARGETS

12. On **June 16, 2016**, at approximately **10:45am**, FDA agents monitored a confidential source (CS) on a controlled telephone conversation to Miriam VALDEZ, at cell phone number xxx-xxx-7845. During the conversation the CS and VALDEZ agreed to meet in the vicinity of the Bank of America parking lot on 1313 NW 36th Street Miami, FL, at approximately 11:00am, in order to buy/sell prescription drugs.

13. CS informed agents prior to this meeting that this was not the first time he/she purchased prescription drugs from VALDEZ, and VALDEZ was the CS' source of prescription drugs for three (3) sales he/she made in the past to other parties.

14. Prior to this meeting, agents confirmed with the State of Florida that VALDEZ is not licensed with the State of Florida to distribute prescription drugs in the state. Furthermore, VALDEZ failed to provide transaction history, transaction information, and transaction statements prior to or at the time of these transactions as required by the FDCA.

15. Prior to these transactions, CS purchased diverted prescription drugs. VALDEZ advised CS she could obtain large quantities of prescription drugs from various sources to be sold for a fraction of the legitimate wholesale acquisition cost ("WAC").

16. At approximately **11:15am**, CS arrived at the Bank of America parking lot on 1313 NW 36th Street Miami, FL. CS then met with VALDEZ and a Hispanic male — who was previously introduced to the CS by VALDEZ as VALDEZ's husband — inside a Silver 2006 Jaguar bearing Florida license plate 64TBJ. At that time, CS agreed to take everything he/she could from VALDEZ's inventory, to include Abilify and all HIV

drugs. The Hispanic male and VALDEZ then informed CS they did not have the prescription drugs with them, but the prescription drugs were at their home. The Hispanic male and VALDEZ further advised they could be back in 10 minutes with the prescription drugs.

17. At approximately **12:10pm**, both the unidentified Hispanic male and VALDEZ arrived at the Bank of America parking lot on 1313 NW 36th Street Miami, FL where they previously met the CS.

18. VALDEZ entered the CS's vehicle and instructed the CS to follow her instructions which were given to VALDEZ by her husband over the phone. According to VALDEZ, she and her husband felt the meet location was too exposed and the authorities could see what they were doing in plain view.

19. At approximately **12:35pm**, CS was instructed by VALDEZ to stop at the west side corner of the intersection of NW 25 Street and 11th Avenue Miami, FL. The CS then parked his/her vehicle behind the 2006 Jaguar where VALDEZ's husband was waiting.

20. VALDEZ exited the CS vehicle and went to the trunk of the 2006 Jaguar which opened. VALDEZ removed a box and a black bag from the Jaguar's trunk and placed them in the passenger section of the CS's vehicle.

21. Once agents observed this transaction, they approached the CS's vehicle and placed VALDEZ into custody.

22. At the same time, the unidentified male (VALDEZ's husband according to the CS) in the 2006 Jaguar fled the scene, evading agents and heading southbound on

11th Avenue at a high rate of speed. For public safety and officer safety reasons, the agents did not pursue.

23. FDA agents later determined the box VALDEZ passed to CS contained diverted prescription drugs due to the glue residue on the bottles and the appearance of having labels previously affixed. In addition, at least one (1) of the prescription drug bottles had a dispensing label still affixed to it. These items were subsequently inventoried.

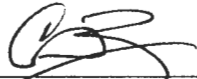
24. After waiving her Miranda rights, VALDEZ admitted that she got the prescription drugs recovered at the scene from people on the street, without being specific as to the identities of her sources.

25. After the inventory was completed, calculations revealed the value of these drugs, according to WAC pricing, was approximately \$102,000.

D. CONCLUSION

WHEREFORE, based on the foregoing, your affiant believes there is probable cause that Miriam VALDEZ did, with intent to defraud and mislead, act as a wholesale distributor of prescription drugs and failed to provide transaction history, transaction information, and transaction statements as required by 21 U.S.C. § 360eee-1(c) (1)(A)(iii) and in violation of 21 U.S.C. §§ 331(t) and 333(a)(2).

FURTHER YOUR AFFIANT SAYETH NOT



CESAR D ZAYAS
Special Agent
United States Food and Drug Administration
Office of Criminal Investigations

SWORN AND SUBSCRIBED TO BEFORE ME
ON THIS 17th DAY OF JUNE 2015 IN MIAMI, FL



HON. JONATHAN GOODMAN
UNITED STATES MAGISTRATE JUDGE